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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,399	09/08/2003	Christopher Fisher	28341/6216.NDV2	3201

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EXAMINER

MOSHER, MARY

ART UNIT PAPER NUMBER

1648

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/657,399

Applicant(s)

FISHER ET AL.

Examiner

Mary E. Mosher, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-14 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/20/04.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

Claims 9-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 9-13 are drawn to a method or reducing HPV E7-induced kinase activity, more specifically to a therapeutic method of ameliorating HPV proliferation in an individual, using an inhibitor of E7-induced CDK2 phosphorylation. The specification describes an assay for finding such an inhibitor, but does not disclose the characteristics of any inhibitory compound, other than the wished-for biological activity. Considering the generic inhibitor recited in the claims, the absence of any inhibitor reduced to practice, and the absence of teachings regarding the physical/chemical characteristics of the desired inhibitor, it is concluded that the specification does not reasonably convey that applicants possessed the inhibitor recited in the claims. This is a "written description" rejection.

Claims 14-15 are drawn to a kit containing packaged components. Applicant points to the Examples and the original claims for support, but the examples and original claims discuss assays, not a manufactured article. If disclosing an assay is the same as disclosing a kit, then does a prior art reference disclosing the same

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components in a different assay constitute disclosure of the claimed kit? This is a "new matter" rejection.

Claims 9-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As discussed above, the specification does not teach any specific inhibitor compounds, or provide guidance on the physical/chemical characteristics required for a compound to be the inhibitor recited in the claims. Furthermore, the specification gives no guidance as to how to administer the inhibitor in a manner that results in the desired therapeutic outcome. The target of the inhibitor is located intracellularly, in keratinized tissue, presenting substantial difficulties regarding penetrating to the target location. Considering the absence of guidance and the absence of working examples, it is concluded that undue experimentation would be required to practice the method as claimed.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Munger et al (US 5736318). Column 8, lines 39-60 describes a kit comprising HPV E7 and histone H1 (which is a CDK2 substrate). Although the reference does not teach the same intended use for the kit, the kit contains components identical to the kit of claim 14.

Therefore it meets each and every limitation of the claim.

Claims 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Nevins et al (US 5650287). Column 11, lines 1-10 describes an assay comprising the Rb protein (which is a CDK2 substrate), HPV E7 protein, and cyclin A. If disclosure of an assay comprising the recited components is sufficient to describe a kit comprising the components, then the reference describes such a kit .

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9/29/05

A handwritten signature in black ink, appearing to read "Mary Mosher".

**MARY E. MOSHER, PH.D.**  
**PRIMARY EXAMINER**